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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/113,561	08/25/1993	THOMAS R. ADAMS	DEKA055	3079

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EXAMINER

FOX, DAVID T

ART UNIT PAPER NUMBER

1638

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/113,561

Applicant(s)

ADAMS ET AL.

Examiner

David T. Fox

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-4 and 67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-4 and 67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's amendment of 18 October 2004 has obviated the indefiniteness and art rejections of record.

Claims 2-4 (newly amended) are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-3 are indefinite for depending upon cancelled claim 68. Dependent claim 4 is included in this rejection, as it does not correct the deficiencies of claim 3.

Claims 2-4 and 67 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated on pages 3-5 of the last Office action for claims 2-4 and 67-68.

Claims 2-4 and 67 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, as stated on pages 5-7 of the last Office action for claims 2-4 and 67-68.

The claims are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest corn transformation with genes encoding fatty acid

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desaturase enzymes, given the lack of availability of said genes at the time of the invention, and the lack of reasonable expectation of success that such genes would function in transformed corn plants to produce a detectable change in oil quality or quantity. Applicant's evidence of unpredictability inherent in corn transformation *per se* at the time of the invention, as discussed by the Somers declaration submitted 18 October 2004 and the references appended to the amendment of 18 October 2004, has been considered, but was not relied upon.

No claim is allowed.

Applicant's arguments filed 18 October 2004 have been fully considered but they are not persuasive.

Applicant urges that the written description rejection is improper, given the failure of the claims to be drawn to genes *per se*, the known availability of the genes to be introduced into the claimed transformed corn plants as evidenced by publications appended to the amendment of 18 October 2004, the lack of a requirement for the specification to describe what is well known in the art, and the suggestions in the specification of how to make and use the claimed transformed corn plants containing fatty acid desaturase genes.

The Examiner maintains that claims drawn to corn plants transformed with a particular gene are inadequately described if the starting material, namely the gene, is itself inadequately described.

See *University of Rochester v. G.D. Searle & Co., Inc.*, U.S. District Court, Western District of New York, Decision and Order No. 00-CV-6161L, decided 05 March

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2003, at page 18, bottom paragraph, which teaches that method claims are properly subjected to a written description rejection if the starting material required by that method is itself inadequately described.

Regarding the alleged availability of the transgenes as of the effective filing date, the Examiner disagrees. All of the references submitted by Applicant were published after April 1990, the effective filing date for the concept of corn transformation. In addition, many of the submitted references were published after August 1993, the effective filing date for corn transformation with fatty acid desaturase genes.

Furthermore, the genus of "fatty acid desaturases" is a broad genus, which encompasses any enzyme of any sequence from any source organism, including plants, bacteria or fungi. Moreover, the genus encompasses enzymes which desaturate a variety of fatty acid substrate types at a variety of substrate positions, e.g. delta-6, delta-9, delta-12, delta-16, etc. No conserved structural features responsible for substrate recognition or catalytic activity have been identified by Applicant, as required by *Lilly*.

In addition, the Examiner disagrees that transformed corn plants containing fatty acid desaturase genes were well known in the art, and that the specification provides evidence of reduction to practice of such plants.

An assay for *finding* a product is not equivalent to a positive recitation of *how to make* a product. Alternatively, disclosure of a method for producing a product does not reduce to practice the product itself. See *Bayer v. Housey*, Appeal No. 02-1598, (Fed.

Cir. 2003), decided 22 August 2003, penultimate page: "processes of identification and generation of data are not steps in the manufacture of a final [drug] product".

Applicant urges that the enablement rejection is improper, given the availability of fatty acid desaturase genes as evidenced by publications appended to the amendment of 18 October 2004, and the evidence of success as demonstrated by the Ursin declaration submitted 18 October 2004.

The Examiner maintains that the instant specification is completely silent with regard to any particular gene encoding any particular fatty acid desaturase. Page 45 of the specification, lines 27-29, merely list desaturases as types of enzymes which are involved in fatty acid biosynthesis. No citations to U.S. patents or even non-patent literature are given or incorporated by reference.

See *Genentech, Inc. v. Novo Nordisk, A/S*, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that disclosure of a "mere germ of an idea does not constitute [an] enabling disclosure", and that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Furthermore, the majority of references submitted by Applicant were published after the effective filing date for corn transformation, and many were published at or after the effective filing date for the use of fatty acid desaturase genes in corn transformation.

See *In re Glass*, 181 USPQ 31, 34 (CCPA 1974), which teaches that references published after the filing date of an application may not be relied upon for the enablement of the specification.

Regarding the Ursin declaration, the Examiner notes that Dr. Ursin utilized fatty acid desaturase genes which were disclosed by a U.S. patent filed in April 1997 which issued in June 2000, well after the effective filing date of the instant invention. Furthermore, Ursin relied upon *Agrobacterium*-mediated corn transformation, which is not the technique disclosed by Applicant. See paragraph number 5 on page 2 of the Ursin declaration. Since the Ursin declaration utilizes genes and transformation techniques not taught by the instant specification, it is insufficient to demonstrate that the specification enabled the claimed invention without the requirement for additional or undue experimentation.

Applicant is also directed to the bottom paragraph of page 9 of the response of 18 October 2004, where Applicant admits that the claimed invention was unpredictable, and where Applicant relies upon the Examiner's previously cited evidence of unpredictability inherent in the obtention of change in oil quality or quantity following corn plant transformation with genes allegedly involved in fatty acid metabolism. In the absence of obtaining an actual change in oil or other phenotype, Applicant has not demonstrated *how to use* the claimed maize plants containing transgenes involved in fatty acid metabolism.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is 571-272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy J. Nelson, Ph.D., can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

January 21, 2005

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

